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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			EXAMINER WARE, DEBORAH K	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/006,102

Applicant(s)

KEETON ET AL.

Examiner

Deborah K. Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-43 is/are rejected.
- 7) ☒ Claim(s) 1-43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☐ Other: _____

DETAILED ACTION

Claims 1-43 are presented for examination on the merits.

Information Disclosure Statement

The Information Disclosure Statements filed May 13, 2002, and April 11, 2003, have been received and entered of record. The references submitted therewith have been considered as indicated on the enclosed PTO-1449 Forms.

Claim Objections

Claims 1-43 are objected to for misspellings of Pseudomonas, as Psuedomonas, and further for non capitalization of Koi in the claims, as well as, improper grammatical representation wherein an bacteria is incorrect sense bacteria refers to more than one bacterium.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 5, 16-17, 19, 21, 23, 25, and 27-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Since the microorganism is recited in the claims, it is essential to the invention recited in those claims. It must therefore be obtainable by a repeatable method set forth in

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the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not apparent if the microorganism is readily available to the public. It is noted that applicants have deposited the organism but there is no indication in the specification as to public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that: (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

(d) the deposit will be replaced if it should ever become inviable.

Applicant is directed to 37 CFR § 1.807(b) which states:

(b) A viability statement for each deposit of a biological material defined in paragraph (a) of this section not made under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure must be filed in the application and must contain:

- (1) The name and address of the depository;
- (2) The name and address of the depositor;
- (3) The date of deposit;
- (4) The identity of the deposit and the accession number given by the depository;
- (5) The date of the viability test;
- (6) The procedures used to

obtain a sample if the test is not done by the depository; and

(7) A statement that the deposit is capable of reproduction.

Applicant is also directed to 37 CFR § 1.809(d) which states:

(d) For each deposit made pursuant to these regulations, the specification shall contain:

- (1) The accession number for the deposit;
- (2) The date of the deposit;
- (3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and
- (4) The name and address of the depository.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite for the recitation of "the reduction of bacterium" at line 1 which is grammatically insufficient and renders the claim unclear and vague. It is suggested to delete "the" at line 1 and insert —a— before "bacterium" at line 1. Also the phrase "an isolated bacteria" recited at line 3, is unclear as to whether the phrase intends one or more biologically pure bacteria. It is suggested to change the phrase to —a biologically pure bacterium— or —biologically pure bacteria—.

Claims 2-3, 7 should be changed accordingly to complement the preferred suggested changes as noted above. It is further suggested that claim 3 not refer to Applicants' strain identifier "EHC 100" and only refer to the deposited accession number instead. Further, claim 7 recites "per milliliter" and it is unclear as to what volume is referred to here, perhaps it is the culture medium from which the *Bacillus cereus* is grown in, but such reference does not appear to be necessary to mention in the claim sense the bacterium has already been grown in culture in order that the density (CFU-colony forming units) was able to be determined therefrom. It is suggested that "per milliliter" be deleted as it is a bit confusing in the claim as to whether it refers to "A probiotic composition" or culture medium for growing and determining the CFUs of the bacterium for the composition.

Claims 15 and 17 are further rendered vague and indefinite for the recitation of "the levels" at line 2, which lacks antecedent basis.

Claim 19 is further suggested to change "the EHC 100" recited at line 2 to the deposited strain identifier instead of Applicants' strain identifier. Also the term strain appears omitted from the claim.

Claim 26 is rendered grammatically indefinite for failing to recite pathogenic bacteria at line 2, or perhaps Applicants intend more than one type of pathogenic bacterium, as indicated in claim 2. Thus, "pathogenic bacterium" recited at line 4 appears to lack antecedent basis as well. It is further suggested to change "pathogenic bacterium" to --pathogenic bacteria--. The same change is suggested for claim 27 and this claim is rendered vague and indefinite as set forth above for claim 26. Also claim 28 is rendered vague and indefinite for the recitation of "the approximate number" because it lacks antecedent basis, and "the" is suggested to be changed to --an--.

Claim 29 also lacks antecedent basis as does claim 28 at line 2 for the recitation of "the levels" and "the" is suggested to be deleted. Claim 29 is further suggested to be changed as noted above for claim 28 for the suggested recitation of --an approximate number--instead. Claim 33 is further rendered vague and indefinite for reasons at noted above for use of similar language, note claim 19 rejection above.

Claim 42 is rendered vague and indefinite for the recitation of "a pathogenic bacteria" at line 1 because it is unclear whether one type of bacterium as suggested by "bacteria", thus, it is suggested to delete "a" before "pathogenic bacteria" at line 1. Further, the recitation of "the percentage" at line 4, lacks antecedent basis and it is suggested to delete "the" and insert --a--. Further, the term "bacterium" recited at line 5, is suggested to be also changed to --bacteria--. Similar changes are suggested for claim 43 as this claim is also rendered vague and indefinite for same reasons as noted above for claim 42.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 7 and 10 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Logan et al. (A), now referred to as Logan.

Claims are drawn to a composition comprising an isolated bacteria of the genus *Bacillus*, of which is further defined to be *Bacillus cereus*. Also the density of colony forming units (CFUs) is defined within a range of 4×10^8 to 6×10^8 . Also the composition is added to an aquatic environment to reduce pathogenic bacteria and this environment can be a Koi pond.

Logan teaches the same, see the abstract, and col. 7, line 28, and also col. 4, line 20.

The claims are identical to the subject matter disclosed by Logan and are thus, considered to be clearly anticipated by the teachings therein.

Claim Rejections - 35 USC § 102/103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3, 4, 5, 6, 14, 15, 16, 17, 18, 19, 20, 21, 26, 27, 28, 29, 32, 33, 34, 35, and 42 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Logan.

Claims are further drawn to a specific strain of *Bacillus cereus* to be comprised by the composition as discussed above. Further, the specific pathogenic bacterium which is desired to be reduced in an aquatic environment using the composition is also set forth to be selected from the group consisting of *Streptococcus*, *Pseudomonas*, and *Aeromonas*. Further, sodium in an amount between 2 to 5% is comprised by the composition. The methods of reducing pathogenic bacteria in an aquatic environment comprises adding an amount of the composition of *Bacillus cereus* or the specific strain thereof to the aquatic environment to cause reduction of the pathogenic bacteria as well as varied steps therein for determining levels of pathogenic bacteria before and after adding the composition and also adding a second dose to cause further reduction of the pathogenic bacteria. The aquatic environment may be not only a Koi pond but also

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saltwater or freshwater. Further, methods of reducing the levels of fish morbidity in an aquatic environment and methods for treating infected fish and infected shellfish are also claimed.

Logan is discussed above, however, in addition Logan teaches combining with the treatment with the composition a salt at 0.3% which is well within the range, note col. 4, line 64. Also the treatment includes testing for pathogens before and after adding additional composition and noted fish mortality and vitality had decreased and increased, respectively, as demonstrated by the fish yield and weight gain. Note, col. 5, all lines. Also note that the composition as disclosed by Logan did not cause or exacerbate bacterial infection of the fish, see col. 5, lines 44-46.

The claims appear to be identical to the the cited disclosure of Logan, discussed above, and are therefore, considered to be anticipated by the teachings therein. However, in the alternative that there is some difference between the specific strain as claimed herein and the strain of *Bacillus cereus* disclosed by Logan then the difference is considered to be so slight as to render the claims directed to the strain as obvious, and further, the reduction in bacteria is considered to be an inherent property of the composition disclosed by Logan and hence any reduction in morbidity and percentage of infected fish, etc. is a function of adding the composition of Logan possessing the inherent property of reducing pathogenic bacteria in an aquatic environment. However, it would have been obvious to one of ordinary skill in the art to expect that pathogenic bacteria would be reduced in an aquatic environment sense Logan clearly teaches that fish yield is increased, thus, percentage infected fish would have been at least expected

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to be decreased and morbidity to also be decreased. Fish yield is an indicator of fish survival in an aquaculture system. Weight gain is an indicator of fish well-being in an aquaculture system. The claims are at least prima facie obvious in the alternative, even if Applicants show that there is some slight difference between what is claimed and what is disclosed by Logan. Hence these claims are at least prima facie obvious over Logan, if some difference is shown between the claims and Logan. The composition of Logan does appear to be reducing pathogenicity in the aquatic environment, especially sense fish yield including infected fish, is/are being increased by adding the composition to an aquatic environment as disclosed by Logan. . Applicant is invited to show that the strains are different by providing a side by side comparison between the strain of the instant claimed invention and the strain of the cited prior art, Logan.

Claim Rejections - 35 USC § 103

Claims 8-9, 11-13, 22-25, 30-31, 36-41 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Logan in view of Hiatt (B) and Villamar (C).

Claims are discussed above but are further drawn to spores of Bacillus, wherein such spores are less than 99% or less than 80%. The pond may be a shrimp pond and other shellfish may be treated as well resulting in a percentage reduction of shellfish upon such treatment. The fish may also be selected from Tilapia.

Hiatt teaches spores of Bacillus cereus comprised by the composition wherein such spores are less than 99% or less than 80%, see col. 5, lines 10-20. The aquatic environment may be fresh water, salt water, fish and fish hatcheries and general marine

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aquacultures, note col. 4, lines 1-5. Also note the abstract and col. 3, lines 1-30.

Sewage sludge may also be treated and reduced and blue green algae (cyanobacteria) too, also see col. 3, lines 31-60.

Villamar teaches aquaculture systems include contained ponds for shellfish, fish and crustaceans, such as shrimp. Note col. 1, lines 10-12 and col. 5, lines 40-45 and col. 7, line 45.

The claims differ from the cited disclosure of Logan in that the claims are further drawn to spores of *Bacillus*, wherein such spores are less than 99% or less than 80%. The pond may be a shrimp pond and other shellfish may be treated as well resulting in a percentage reduction of shellfish upon such treatment. The fish may also be selected from *Tilapia*.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to select for a *Bacillus cereus* containing composition as disclosed by Logan and spores thereof for use in aquatic environments including fresh water, salt water, fish and fish hatcheries, shellfish, as well as shrimp and general marine aquacultures as disclosed by Hiatt and Villamar in order to reduce pathogenic bacteria in the aquatic environment. The reduction of pathogens in the environment is an inherent property of the composition disclosed by Logan, however, Hiatt clearly teach reducing cyanobacteria (blue green algae) and sludge by using the *Bacillus* containing composition of Hiatt.

Clearly one of skill in the art would have expected successful results of reducing pathogenic bacteria in the aquatic environments using the composition containing

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Bacillus cereus and strains thereof as well as spores thereof. Hiatt clearly teach that the spores are in an amount of less than 99% or 80%. Thus, to combine in the composition of Logan these amounts of spores is clearly within the skill of an ordinary artisan. To treat shrimp and select for Tilapia fish to be treated is an obvious modification of the cited prior art and such aquaculture systems are well known as taught by Hiatt and Villamar. Clearly one of skill in the art would have been motivated to select for the spore amounts and aquatic environments disclosed by Hiatt and Villamar. Note Villamar also disclose using spores of Bacillus in their composition. The claims are prima facie obvious over the cited prior art because successful results would have been expected by one of skill in this art.

Claim Rejections - 35 USC § 102

Claims 1-2, 11, 13, 14, 22, 24, 26, 38 and 40 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hiatt.

Claims are discussed above.

Hiatt is discussed above.

The claims are identical to the cited Hiatt disclosure and are therefore, considered to be clearly anticipated by the teachings therein.

Claim Rejections - 35 USC § 102/103

Claims 3, 16, 23, 25, 27, 39, 41 and 42 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hiatt.

Claims and Hiatt are discussed above.

Claims are considered to be identical to the cited disclosure of Hiatt and are therefore, considered to be anticipated by the teachings therein. However, in the alternative that there is some difference between the strain as claimed herein and the *Bacillus cereus* disclosed by Hiatt then such difference is considered to be so slight as to render the claims prima facie obvious over the cited reference. Applicant is invited to show that the strains are different by providing a side by side comparison between the strain of the instant claimed invention and the strain of the cited prior art, Hiatt. Thus, the claims are alternatively rendered prima facie obvious over Hiatt in the off chance case that there is some difference between the prior art and the claimed strain.

Claim Rejections - 35 USC § 103

Claims 4-10, 12, 15, 17-21, 28-37 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiatt in view of Nader et al (also referred to as Nader), Logan, and Villamar.

Claims are discussed above as are Hiatt, Logan and Villamar.

Nader teaches sludge contains pathogenic bacteria: *Aeromonas* and *Pseudomonas*. See Figure 1.

The claims differ from Hiatt for reasons as noted above, but also because the specific pathogenic bacteria selected from *Aeromonas* or *Pseudomonas* or *Streptococcus* is not clearly disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to reduce pathogenic bacteria such as that found in sludge as also disclosed by Hiatt and Nader of which Nader do clearly disclose *Aeromonas* and/or *Pseudomonas* as being contained in sludge, and further using the composition added to aquatic environments as disclosed by Hiatt, Nader, Logan and Villamar. Clearly Logan teaches the desired CFUs to be contained by the composition and Villamar teaches varied aquatic environments for which one of skill may select from and expect successful results. The motivation to combine the prior art references is taken from whole teachings within each reference and the fact that Hiatt clearly teaches the desire to reduce pathogenic bacteria.

Sludge would have been expected to contain the *Aeromonas* or *Pseudomonas* and further to degrade these is clearly within the skill of an artisan and well known. *Bacillus* is added in the form of spores to the sludge as disclosed by Hiatt and reduces the sludge, hence reduction of *Aeromonas* and *Pseudomonas* would have been expected. The motivation to combine the references is clear on the above teachings. One of skill would have known that sludge contains bacteria to be degraded. Upon reading the disclosure of Hiatt one of skill would have known that *Bacillus cereus* degrades sludge and hence would have expected successful results for reducing bacteria contained in the sludge. Nader clearly teaches the same bacteria to be reduced in the sludge as claimed. No unexpected successful result is obtained by Applicants' claimed invention. Therefore, the claims are rendered *prima facie* obvious over the cited prior art.

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All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.


The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 308-4245. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 308-4743. The fax phone number for the organization where this application or proceeding is assigned is 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0196.


DEBORAH K. WARE
PATENT EXAMINER
Deborah K. Ware
December 8, 2003